IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

LAVOIE-FERN, ET AL., Plaintiffs, v. THE HERSHEY COMPANY, Defendant.	Case No. 1:21-cv-01245 (Judge Sylvia H. Rambo)

BRIEF IN SUPPORT OF
DEFENDANT THE HERSHEY COMPANY'S MOTION TO DISMISS
PURSUANT TO RULE OF CIVIL PROCEDURE 12(b)(6)

TABLE OF CONTENTS

Page

I. PROCEDURAL HISTORY 1

II. STATEMENT OF FACTS 1

A. Plaintiffs' Allegations. 1

B. Relevant Regulations and Legislative History. 2

III. STATEMENT OF QUESTIONS INVOLVED 4

IV. LEGAL ARGUMENT 4

A. Plaintiffs' State Tort Law Claims Are Expressly Preempted Because They Seek to Impose Obligations That Are Not Identical to the Requirements of 21 U.S.C. § 343(i)(2). 5

B. The NLEA's Safety Exception is Inapplicable Because FDA Has Affirmed Glycyrrhizin is GRAS. 10

C. Any Allegation that Defendant Should Not Have Used Glycyrrhizin is Conflict Preempted. 11

V. CONCLUSION 12

TABLE OF AUTHORITIES

Page(s)

CASES

Babcock & Wilcox Co. v. Kan. City S. Ry. Co.,
557 F.3d 134 (3d Cir. 2009) 2

Backus v. Nestle USA, Inc.,
167 F. Supp. 3d 1068 (N.D. Cal. 2016).....12

Beasley v. Lucky Stores, Inc.,
400 F. Supp. 3d 942 (N.D. Cal. 2019).....12

In re Bisphenol-A (BPA) Polycarbonate Plastic Prod. Liab. Litig.,
No. 08-1967-MD-W-ODS, 2009 WL 3762965 (W.D. Mo. Nov. 9, 2009) 10

Chic. Faucet Shoppe, Inc. v. Nestle Waters N. Am. Inc.,
24 F. Supp. 3d 750 (N.D. Ill. 2014).....10

Cmty. Legal Servs., Inc. v. Legal Servs. Corp.,
CIV. A. 86-3617, 1986 WL 10648 (E.D. Pa. Sept. 29, 1986).....2

Farina v. Nokia Inc.,
625 F.3d 97 (3d Cir. 2010) 4, 5

Geier v. Am. Honda Motor Co.,
529 U.S. 861 (2000).....11

Gubala v. CVS Pharmacy, Inc.,
No. 14 C 9039, 2015 WL 3777627 (N.D. Ill. June 16, 2015).....7, 10

Hawkins v. Kellogg Co.,
224 F. Supp. 3d 1002 (S.D. Cal. 2016) 12

Mills v. Giant of Md., LLC,
441 F.Supp.2d 104 (D.D.C.2006).....10

In re Morgan Stanley Smith Barney LLC Wage & Hour Litig.,
CIV. 2:11-03121 WJM, 2012 WL 6554386 (D.N.J. Dec. 14, 2012) 2

Nemphos v. Nestle Waters N. Am., Inc.,
775 F.3d 616 (4th Cir. 2015) 9

Turek v. Gen. Mills, Inc.,
754 F. Supp. 2d 956 (N.D. Ill. 2010), *aff'd as modified*, 662 F.3d
423 (7th Cir. 2011).....7, 8, 9

Winter v. Pa. State Univ.,
172 F.Supp.3d 756 (M.D. Pa. 2016).....2

STATUTES, RULES & REGULATIONS

21 C.F.R. § 100.1(c)(4)(i) 6

21 C.F.R. § 101.4(a)(1).....6

21 C.F.R. § 102.5(a).....6

21 C.F.R. § 102.5(d) 6

21 C.F.R. § 184.1408 3

42 Fed. Reg. 39117–119 (Aug. 2, 1977) 3

48 Fed. Reg. 54983-02, 1983 WL 171904(F.R.) (Dec. 8, 1983).....3, 4, 9

50 Fed. Reg. 21043-01, 1985 WL 144933(F.R.) (May 22, 1985).....3

21 U.S.C. § 321(s).....3

21 U.S.C. § 343–1 6

21 U.S.C. § 343–1(a)(2).....6

21 U.S.C. § 343(i)(2) 5, 6

21 U.S.C. § 348 3

Fed. R. Civ. P. 12 1

Pub L. No. 101-535, 104 Stat. 2353 (1990), *codified as amended* at 21
U.S.C. §§ 301, 321, 337, 343, 371.....5

Pub. L. No. 101–535, § 343-1(c)(2).....10

OTHER AUTHORITIES

H. Rep. No. 101-538, 1990 U.S.C.C.A.N. 3336 (June 13, 1990) 6

FDA Guidance for Industry: Food Labeling Guide, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide 2

I. PROCEDURAL HISTORY

Plaintiffs filed the Complaint in this action on July 15, 2021. Compl. (Doc. 1). Thereafter, an executed Waiver of the Service of Summons was filed on October 5, 2021. Waiver (Doc. 6). Defendant, The Hershey Company, is required to file and serve an initial response to the Complaint on or before December 6, 2021. The Hershey Company has filed a Motion to Dismiss pursuant to Federal Rule of Civil Procedure 12. This memorandum is being submitted in support of that motion.

II. STATEMENT OF FACTS

A. Plaintiffs' Allegations.

Plaintiffs are four individuals from four different states - Washington, Tennessee, Florida, and Massachusetts. Compl. (Doc. 1) ¶¶ 1-4. Plaintiffs each allege that their consumption of Good & Plenty candy or Twizzlers Black Licorice caused them to suffer injuries. Compl. (Doc. 1) ¶¶ 26-70. In particular, they allege that Good & Plenty candy and Twizzlers Black Licorice contain the ingredient glycyrrhizin or licorice extract which they allege "can have very harmful effects on the body." Compl. (Doc. 1) ¶¶ 9-11. Plaintiffs bring claims for strict products liability and negligence, contending that the products are defective because Hershey should have either used a different ingredient or provided a warning on the product label. Compl. (Doc. 1) ¶¶ 71-94. Specifically, at paragraph 24,

Plaintiffs complain that the subject products do not contain a warning "that consumption of the black licorice product can lead to heart conditions, low potassium, or any of the other conditions described." Compl. (Doc. 1) ¶ 24.

B. Relevant Regulations and Legislative History.[1]

"The Food and Drug Administration (FDA) is responsible for assuring that foods sold in the United States are safe, wholesome, and properly labeled." *See* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide (attached as Ex. 3). Any substance intentionally added to food is subject to premarket review and approval unless the substance is "generally recognized as safe" (GRAS) by qualified experts under the intended conditions of use. GRAS status is established through scientific procedures or, in the case of a substance widely used in food prior to 1958, through

[1] "In evaluating motions to dismiss, courts consider allegations in the complaint, exhibits attached to the complaint, matters of public record, and documents that form the basis of a claim. . . . This includes legislative history. . . ." *In re Morgan Stanley Smith Barney LLC Wage & Hour Litig*., CIV. 2:11-03121 WJM, 2012 WL 6554386, at *2 (D.N.J. Dec. 14, 2012) (internal citations and quotations omitted) (attached as Ex. 1). *See also Babcock & Wilcox Co. v. Kan. City S. Ry. Co.*, 557 F.3d 134, at 137 (3d Cir. 2009) (considering legislative and regulatory history of statute to determine whether lower court had subject matter jurisdiction); *Winter v. Pa. State Univ.,* 172 F.Supp.3d 756, 775 (M.D. Pa. 2016) (analyzing Supreme Court's review of the legislative history of Title VII when determining whether plaintiff's claims are preempted); *Cmty. Legal Servs., Inc. v. Legal Servs. Corp*., CIV. A. 86-3617, 1986 WL 10648, at *1 (E.D. Pa. Sept. 29, 1986) (analyzing legislative history of Legal Services Corporation Act to determine whether to grant motion to dismiss) (attached as Ex. 2).

scientific procedures *or* experience based on common use in food. *See generally* 21 U.S.C. § 348; 21 U.S.C. § 321(s) (defining food additive). In the case of glycyrrhizin or licorice extract, FDA evaluated available safety information for the substance and in 1985 affirmed its GRAS status subject to specific quantity limitations. *See* 21 C.F.R. § 184.1408; 50 Fed. Reg. 21043-01, 1985 WL 144933(F.R.) (May 22, 1985) (attached as Ex. 4).

Glycyrrhizin was "evaluated under [a] comprehensive safety review . . . conducted by the [FDA]" which included a comprehensive review of the scientific literature. 42 Fed. Reg. 39117–119 (Aug. 2, 1977) (attached as Ex. 5). As part of its review, FDA considered various comments from the public. 48 Fed. Reg. 54983-02, 1983 WL 171904(F.R.) (Dec. 8, 1983) (attached as Ex. 6). One comment considered by FDA "requested that the agency take action to reduce the potential hazard that licorice presents to the public and included several published reports of licorice toxicity to support the request." *Id.* at *54985. The data submitted showed "several reports of human toxicity following chronic consumption of high levels of licorice." *Id.* FDA stated that "[it] was aware, even before it received these reports, that these types of toxicity have been associated with ingestion of licorice" including the potential for a hypertensive effect. *Id.* FDA stated that "the levels of glycyrrhizin contained in foods do not pose a hazard to the public, provided that foods that contain glycyrrhizin are not consumed in

excessive quantities." *Id.* FDA ultimately found that the data "underscore[d] the need to limit the consumption of glycyrrhizin but do not indicate a need to change its status as a GRAS ingredient." *Id.* FDA "conclude[d] that the available information establishes that specific limitations on the use of licorice and ammoniated glycyrrhizin in food are appropriate, but that no further change in the regulatory status of these ingredients is warranted." *Id.* Plaintiffs' Complaint makes no allegations that the amount of glycyrrhizin in Twizzlers' Black Licorice or Good & Plenty candy exceeds the permissible limits imposed by FDA.

Moreover, as Plaintiffs admit, these safety concerns have continued to be on FDA's radar, Compl. (Doc. 1) ¶ 15; however, FDA has not moved to revoke or otherwise modify glycyrrhizin's GRAS status.

III. STATEMENT OF QUESTIONS INVOLVED

Question: Are Plaintiffs' state tort law claims preempted by federal law?

Suggested Answer: Yes.

IV. LEGAL ARGUMENT

The Supremacy Clause of the United States Constitution invalidates state law that interferes with or is contrary to federal law. *Farina v. Nokia Inc.*, 625 F.3d 97, 115 (3d Cir. 2010). Federal law can preempt state law through express preemption or conflict preemption. *Id.* "Express preemption applies where Congress, through a statute's express language, declares its intent to displace state

law." *Id.* "Conflict preemption nullifies state law inasmuch as it conflicts with federal law, either where compliance with both laws is impossible or where state law erects an 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Id.* (citation omitted). "Federal regulations preempt state laws in the same fashion as congressional statutes." *Id.*

Plaintiffs' claims – and the underlying relief sought (mandatory food labeling and/or alteration of GRAS ingredients) – directly conflicts with FDA's role under federal law to establish a uniform, national policy for food safety.

A. Plaintiffs' State Tort Law Claims Are Expressly Preempted Because They Seek to Impose Obligations That Are Not Identical to the Requirements of 21 U.S.C. § 343(i)(2).

Plaintiffs do not allege that Defendant's labeling is anything other than truthful and in full compliance with FDA regulations. Instead, by way of their state tort law claims, Plaintiffs impermissibly seek to impose additional and separate labeling requirements that go far beyond those the FDA specifically determined were appropriate and required.

The Nutrition Labeling and Education Act ("NLEA") is a 1990 amendment to the Federal Food, Drug, and Cosmetic Act ("FDCA"),[2] regulating food labeling. Congress enacted the NLEA to "establish uniform national standards" for the

[2] *See* Pub L. No. 101-535, 104 Stat. 2353 (1990), *codified as amended* at 21 U.S.C. §§ 301, 321, 337, 343, 371.

information displayed on food labels. H. Rep. No. 101-538, 1990 U.S.C.C.A.N. 3336, 3342 (June 13, 1990) (attached as Ex. 7). To ensure uniformity in food labeling, the NLEA expressly preempts state laws to the extent they are "not identical to" certain provisions of the NLEA. *See generally* 21 U.S.C. § 343–1. "Not identical to" means that the state requirement "directly *or* indirectly imposes obligations … that. . . are not imposed by or contained in the applicable provision (including any implementing regulation) of section 401 or 403 of the act." *See* 21 C.F.R. § 100.1(c)(4)(i) (emphasis added).

In particular, the NLEA provides "no State . . . may directly or indirectly establish . . . any requirement for the labeling of food of the type required by section . . . 343(i)(2) . . . of this title that is not identical to the requirement of such section." 21 U.S.C. § 343–1(a)(2). Section 343(i)(2) requires food labels to list the "common or usual name" of each "ingredient" in the food "in descending order of predominance by weight." 21 U.S.C. § 343(i)(2). *See also* 21 C.F.R. § 101.4(a)(1). Under the applicable regulations, the "common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients." 21 C.F.R. § 102.5(a). The common or usual name may be established by regulation or common usage. 21 C.F.R. § 102.5(d).

Here, Plaintiffs seek to have Defendant do more than list the "common or usual name" with respect to the ingredient glycyrrhizin. Plaintiffs claim that without some unspecified warning language regarding the health effects of ingesting large amounts of glycyrrhizin, Hershey's products are defective.[3] Inclusion of any such warning language would be at odds with express preemption provisions contained in the regulatory scheme implemented pursuant to the NLEA and the FDCA. Plaintiffs' claims are therefore expressly preempted.

Other District and Circuit Courts of Appeal that have addressed this issue have held that a plaintiff's claims are preempted where they seek to impose requirements not identical and "materially different from the current NLEA requirements." *Turek v. Gen. Mills, Inc.*, 754 F. Supp. 2d 956, 961–62 (N.D. Ill. 2010), *aff'd as modified*, 662 F.3d 423 (7th Cir. 2011); *see also Gubala v. CVS Pharmacy, Inc.*, No. 14 C 9039, 2015 WL 3777627, at *4 (N.D. Ill. June 16, 2015) (finding plaintiffs' claims preempted because they "would require defendants to label their products in a particular way," but "[t]he NLEA does not include such a labeling requirement") (attached as Ex. 8). In *Turek*, the plaintiffs took issue with

[3] State product liability law from each of the Plaintiffs' four states requires proof that a product is defective or unreasonably dangerous as a threshold matter. Here, it defies logic to suggest that either or both Twizzlers or Good & Plenty candies are defective or unreasonably dangerous when it is undisputed that the products contain no more than the FDA approved amount of an ingredient that the FDA has considered, evaluated, and found to be GRAS.

the labeling for defendant's "chewy bars" which stated that the bars contained "35% of your daily fiber." *Turek*, 662 F.3d at 425–26. The plaintiffs alleged that the principal fiber in the "chewy bars" was inulin from chicory root which allegedly provides fewer benefits than other fiber, causes stomach issues, and is harmful to women who are pregnant or breast feeding. *Id.* Although the label listed inulin from chicory root in the ingredients section of the label, the plaintiffs alleged defendant should have done more and stated that "the product contains a form of fiber that is inferior to 'natural fiber' and actually harmful to some consumers." *Id.* at 426.

The district and appellate courts examined the regulations regarding statements relating to fiber and found that the "chewy bars'" labeling was compliant with the regulations. *Id.* at 427. The court held the plaintiffs' claims were expressly preempted because "[t]he disclaimers that the plaintiff want[ed] added to the labeling of defendants' inulin-containing chewy bars [was] not identical to the labeling requirements imposed on such products by federal law." *Id.* In particular, the court stated that the relevant regulations do not require disclosing whether a fiber product includes inulin or that products containing inulin produce fewer health benefits or should not be consumed by certain populations. *Id.*

As in *Turek*, here Plaintiffs seek to use state law to require Defendant to add disclaimers or warnings to Twizzlers black licorice and Good & Plenty candy that go beyond what is required by the relevant regulations. Such claims are plainly preempted. Allowing Plaintiffs to use state law to impose state specific disclosure requirements raises the concern identified in *Turek*, that "[m]anufacturers might have to print 50 different labels, driving consumers who buy food products in more than one state crazy." *Id* at 426.

Moreover, preemption is particularly appropriate in a case like this where FDA has previously considered the alleged toxicity of glycyrrhizin. In *Nemphos v. Nestle Waters N. Am., Inc.*, 775 F.3d 616 (4th Cir. 2015), plaintiff alleged that defendant failed to warn about the risks of dental fluorosis. The court granted defendant's motion to dismiss and held such claims were expressly preempted because bottled water was subject to a standard of identity. *Id.* at 625. The court considered the fact that in establishing "the standard of identity for bottled water in 1995, the FDA actually addressed several issues involved in fluoride consumption, including the notion of a warning requirement regarding dental fluorosis." *Id.* at 623. The FDA, however, declined to mandate a warning about the risks of dental fluorosis and instead set acceptable fluoride levels for bottled water. *Id.*

Similarly, here, when determining whether to affirm the GRAS status of glycyrrhizin, FDA considered "the potential hazard that licorice presents to the

public and . . . several published reports of licorice toxicity." 48 FR 54983-02 (attached as Ex. 6). Ultimately, FDA found that the appropriate action was to set specific limitations on the use of glycyrrhizin in foods and rejected warnings. *See also Gubala*, 2015 WL 3777627, at *4 ("Further supporting preemption . . . is the fact that the FDA specifically considered and rejected a proposal to enforce stricter requirements for labeling products" along the lines of what plaintiffs sought) (attached as Ex. 8); *Chic. Faucet Shoppe, Inc. v. Nestle Waters N. Am. Inc.*, 24 F. Supp. 3d 750, 758 (N.D. Ill. 2014) (holding disclosure requirement preempted and considering that "[d]uring the rulemaking process, the FDA considered but rejected a disclosure requirement.").

B. The NLEA's Safety Exception is Inapplicable Because FDA Has Affirmed Glycyrrhizin is GRAS.

The NLEA provides that its express preemption provision "shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food." Pub. L. No. 101–535, § 343-1(c)(2) (attached as Ex. 9). This exception, however, is inapplicable where, as here, FDA has concluded use of glycyrrhizin is "safe" within the specified limits. *See In re Bisphenol-A (BPA) Polycarbonate Plastic Prod. Liab. Litig.*, No. 08-1967-MD-W-ODS, 2009 WL 3762965, at *6 (W.D. Mo. Nov. 9, 2009) (holding safety exception inapplicable where "FDA has concluded that the use of BPA in epoxy liners is 'safe' so long as the manufacturer

abides by the FDA's prescribed conditions.") (attached as Ex. 10); *Mills v. Giant of Md., LLC*, 441 F.Supp.2d 104, 108–09 (D.D.C.2006) (holding that lactose intolerant plaintiffs could not invoke safety exception to save claims against milk producers for failure to warn where FDA had considered plaintiffs' symptoms and concluded that plaintiffs' condition did not implicate safety concerns).

As noted above, there are no allegations in this case, nor could there be, that the products ingested by these Plaintiffs contained an amount of glycyrrhizin above the limits provided for by the applicable FDA regulations. Therefore, the limited exception to preemption is inapplicable and Plaintiffs' claims should be dismissed because they are expressly preempted by federal law.

C. Any Allegation that Defendant Should Not Have Used Glycyrrhizin is Conflict Preempted.

In passing, Plaintiffs suggest that Defendant should have used an ingredient other than glycyrrhizin. Compl. (Doc. 1) ¶¶ 13, 14, 23, 83, 93. To the extent Plaintiffs' claims are premised on this argument, they are nonetheless conflict preempted as they would conflict with the agency's decision affirming the GRAS status of this ingredient in specific quantities. Where a federal regulatory agency like FDA has regulated in an area of its expertise pursuant to a legal mandate, state law may not be used to bar conduct the agency has chosen not to prohibit. If state law were able to bar such conduct, the threat of liability pursuant to state law would create an obstacle to the accomplishment of the comprehensive and

carefully created federal regulatory program. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881-82 (2000) (stating that federal law that required new cars to employ passive-restraint systems preempted state tort claims that would have required manufacturers to install air bags in all new cars); *Backus v. Nestle USA, Inc.*, 167 F. Supp. 3d 1068, 1071 (N.D. Cal. 2016) (tort suit imposing liability for presence of ingredient in food would impose liability for something federal law permitted); *Beasley v. Lucky Stores, Inc.*, 400 F. Supp. 3d 942, 953 (N.D. Cal. 2019) (similar and stating that such claims would "conflict with Congress's decision not to deem [the oils] unsafe, or the food containing them adulterated" until a certain date); *Hawkins v. Kellogg Co.*, 224 F. Supp. 3d 1002, 1016 (S.D. Cal. 2016) (same).

V. CONCLUSION

Based on the foregoing, Defendant respectfully requests that the Court grant Defendant's motion.

Date: December 3, 2021

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CERTIFICATE OF SERVICE

The foregoing submission has been electronically filed with this Court this 3rd Day of December, 2021. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Parties may access this filing through the Court's system.

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